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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/814,490 | 03/29/2004 | Robert G. Johnson JR. | 010083.02 | 8300 |

7590 03/28/2008
Gary W. Ashley
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| EXAMINER |
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HAGOPIAN, CASEY SHEA

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| ART UNIT | PAPER NUMBER |
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1615

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| MAIL DATE | DELIVERY MODE |
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03/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/814,490 | Applicant(s) JOHNSON, ROBERT G. | |
| | Examiner CASEY HAGOPIAN | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,14,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,14,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 12/19/2007.

Claims 5, 14, 19 and 20 are amended. Claims 1-4, 7-13 and 15-18 are cancelled. Claims 5, 6, 14, 19 and 20 are currently pending.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 6/29/2007:

Claim Objections

Claim 6 stand objected to because of the following informalities: the claim is missing a "." at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1615

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 6, 14, 19 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ashley et al. (US 2003/0045711 A1) in view of Carlyle et al. (US 2002/0127263 A1).

Ashley teaches coated stents to treat restenosis, the coating including a therapeutic agent comprising a derivative of epothilone D (paragraphs 0004 and 0250-0251).

Ashley is silent to rapamycin and a polymer.

Carlyle teaches compositions and methods thereof comprising at least one thiazolidinedione in combination with at least one additional therapeutic agent for the treatment of restenosis (abstract, paragraph 0028, and claims 22 and 24-25). In particular, Carlyle teaches coated stent comprising said compositions. Carlyle also

Art Unit: 1615

teaches rapamycin (paragraph 0028). Rapamycin is well known in the art to be effective alone or in conjunction with other therapeutic agents against restenosis. Carlyle further teaches polymers including polycaprolactone, polyethylene glycol, and poly-L-lactic acid (paragraph 0011).

One of ordinary skill in the art would have been motivated to either replace or combine compounds taught in the relevant art as being able to treat the same disorder because they are appreciated as equivalents among the art. Absent of unexpected results, a practitioner would have reasonably expected a medical device comprising a composition comprising one or medicaments capable of treating restenosis. Thus, in Ashley, it would have been obvious to one skilled in the art at the time the invention was made to include rapamycin as suggested by Carlyle into the coated medical device in order to treat restenosis.

One of ordinary skill in the art would have been motivated to include a polymer into the coating of a medical device because the polymer would control the elution rate of the compounds. A practitioner would have reasonably expected a medical device coating with a composition containing a polymer and one or more therapeutics capable of various release profiles depending on the polymeric formulation. Thus, in Ashley, it would have been obvious to one skilled in the art at the time the invention was made to include a polymer as suggested by Carlyle in order to control the release of said compounds.

Response to Arguments

Applicant's amendments render the rejections under 35 USC § 102 moot, namely because the currently amended claims now require rapamycin and both Ashley and Santi are silent to rapamycin. Thus, said rejections under 35 USC § 102 are withdrawn.

Applicant's arguments with regards to the rejection under 35 USC § 103 have been fully considered but they are not persuasive. Applicant argues that Ashley is not citable as a reference under §103. In response, it is respectfully submitted that Ashley qualifies as prior art under §103 because Ashley was published before the instant application claims benefit. It is noted that in the previous Office Action dated 6/29/2007, Ashley qualified as prior art under both §102 (a) and (e). Ashley was published on March 6, 2003 and the instant application claims benefit to March 28, 2003; thus, Ashley can be utilized as a reference under §103. For these reasons, applicant's arguments are found unpersuasive. Thus, rejection under 35 USC § 103 is maintained.

Conclusion

All claims have been rejected; no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/814,490
Art Unit: 1615

Page 7

/Casey Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615